

REMARKSObjection under 35 U.S.C. §132

The Examiner objects to the amendments to pages 1, 2 and 8 to insert "polyclonal" with the assertion that there is no support for the amendment in the originally filed disclosure. The Examiner further asserts that Example 3(c) fails to provide support because Example 3(c) is merely one step in the process of making monoclonal antibodies and that the hybridomas in Example 3(e) produce monoclonal antibodies. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

It is well established that there does not have to be *ipsis verbis* support in the specification for amendments made to specification or claims. *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989). More recently the Federal Circuit addressed the issue of new matter in *All Dental Prodx LLC v. Advantage Dental Products Inc.*, 64 USPQ2d 1945 (Fed. Cir. 2002). In *All Dental*, the Federal Circuit held that the determination of whether a newly added term is new matter is whether "one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented."

Despite the recitation of "monoclonal" in the specification, one skilled in the art would readily recognize that polyclonal antibodies are also part of the invention. In fact, the disclosure

of monoclonal antibodies supports the inclusion of polyclonal antibodies because one cannot obtain a monoclonal antibody without first obtaining polyclonal antibodies. As shown in Example 3(c) of the specification, polyclonal antibodies were produced in a mouse by the inventors. The inventors used the spleen cells producing the polyclonal antibodies for clonal expansion to generate monoclonal antibodies and it is clear from the specification that polyclonal antibodies were also generated in the Example.

In addition, polyclonal antibodies were generated with the karo-splenocytes of Example 3(d) and the hybridomas of Example 3(e). This is evident from the discussion on page 23, lines 6-8 of Example 3(f), wherein it is indicated that hybridomas in wells that were positive for binding to individual peptides were obtained by limited serial dilution. Thus, the hybridomas in Example 3(e) did not produce monoclonal antibodies as asserted by the Examiner, but rather polyclonal antibodies.

One skilled in the art would readily recognize from reading the specification that the inventors obtained polyclonal antibodies. As such, the amendment to the specification to insert the term polyclonal antibody is not new matter, but simply the explicit recitation of what is already disclosed and described in the Examples. Withdrawal of the new matter rejection is therefore respectfully requested.

Objections under 37 C.F.R. §1.75

Claims 18-20 have been objected to under 37 C.F.R. 1.75 as being duplicative of claims 13-15. The Examiner asserts that both claims 13 and 18, for example, are drawn to the DNA of SEQ ID NO:2. Claims 18-20 have been cancelled, thus obviating this objection. In addition, new claims 23-26 have been added. Support for new claims 23-26 may be found in the original claims. In addition, support for the recitation of hybridization conditions may be found on page 13 of the specification. Support of the wash condition of 0.15M NaCl is found with the disclosure on page 17 that 3XSSC contains 0.45M. The wash conditions on page 13 use 1XSSC, thus 0.15M NaCl. As such, new claims 23-26 are fully supported and no new matter has been added.

Rejections under 35 U.S.C. §101

Claims 13 and 18 have been rejected under 35 U.S.C. §101 as being drawn to a product of nature and therefore being improper. Claim 13 has been amended to recite, "An isolated DNA...."

Rejections under 35 U.S.C. §112, second paragraph

Claims 15 and 20 have been rejected under 35 U.S.C. §112, second paragraph as being unclear. More specifically, claims 15 and 20 have been rejected as being indefinite for recitation of "host cell harboring a plasmid." Claim 15 has been amended to

recite "host cell transformed with a plasmid." Withdrawal of the rejection is therefore respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the MaryAnne Armstrong, PhD (Reg. No. 40,069) at the telephone number listed below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

A marked-up version of the amended claims showing all changes is attached hereto.

Applicants request a one (1) month extension of time for filing the present response. The required fee is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGESIN THE CLAIMS

Claims 16-22 have been cancelled without prejudice of disclaimer of the subject matter contained therein.

Claims 13-15 have been amended as follows.

13. A An isolated DNA having ~~the nucleotide sequence shown in SEQ ID NO: 2 which corresponds to the amino acid sequence of a~~ which encodes a membrane-type matrix-metalloproteinase, comprising amino acid sequences from amino acid numbers 160 to 173, 320 to 333 and from 498 to 512 and ~~characterized by~~ a continuous sequence of hydrophobic amino acids peculiar to membrane-binding proteins from amino acid number 533 to 562 in the C terminus domain shown in SEQ ID NO: 1, ~~having the amino acid sequence from amino acid number 160 to 173, 320 to 333 and from 498 to 512 shown in SEQ ID NO: 1 or having the amino acid sequence from amino acid number 1 to 173, 320 to 333, 498 to 512 and 563 to 582 shown in SEQ ID NO: 1.~~

14. A plasmid containing a the isolated DNA according to any one of claims 13 or 23-26 ~~claim 13 having the nucleotide sequence shown SEQ ID NO: 2.~~

15. A host cell ~~harboring~~ transformed with a plasmid according to claim 14 ~~containing a DNA having the nucleotide sequence shown in SEQ ID NO: 2.~~

New claims 23-26 have been added.